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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,754	03/19/2001	Christopher Ed Schuler	GC-425	8075

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EXAMINER
MAYNARD, JENNIFER J

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/811,754	Applicant( ) ED SCHULER, CHRISTOPHER	
	Examiner Jennifer J Maynard	Art Unit 3763	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. ,See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

Claim 3 is objected to because of the following informalities: line 1 recites "...treating of an said eye disorder...", the phraseology is semantically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed range of "at least 10 Turbidity Reducing Units (TRU)" has not been adequately disclosed in the written description of the invention. The Examiner only found one reference of a range of 152 to 218 TRU in the specification on Page 7, line 4.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 152 to 218 TRU, does not reasonably provide enablement for at least 10 TRU. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The Examiner questions the criticality of the TRU when such a large discrepancy exists between the claimed range and that which is disclosed in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (US 5,792,103 A).

Schwartz et al. discloses a method of intraocularly injecting a mixture of chrondroitin sulfate, hyaluronic acid and hyaluronidase derived from *Streptomyces*, see Column 7, lines 61-65.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karageozian et al. (US 5,866,120 A) in view of Schwartz et al. (US 5,792,103 A), and further in view of Kaneko et al. (US 3,728,223 A).

Karageozian et al. discloses the use of hyaluronidase to accelerate the clearance of hemorrahgic blood from the vitreous humor.

Karageozian et al. fails to disclose the use of hyaluronidase derived from *Streptomyces hyalurolyticus*.

Schwartz et al. discloses a method of intraocularly injecting a mixture of chrondroitin sulfate, hyaluronic acid and hyaluronidase derived from *Streptomyces*, see Column 7, lines 61-65. Thus

It would have been obvious to one having ordinary skill in the art to have modified Karageozian et al.'s method by utilizing an alternative source of biocompatible hyaluronidase, such as hyaluronidase isolated from *Streptomyces* taught by Schwartz.

Additionally, Schwartz et al. does not specify the species of *Streptomyces* utilized, however the Examiner believes that it would have been obvious to one having ordinary skill in the art to have utilized *Streptomyces hyalurolyticus* as taught by Kaneko et al., as it was a readily known source of hyaluronidase.

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (US 5,626,865 A) in view of Schwartz et al. (US 5,792,103 A), and further in view of Kaneko et al. (US 3,728,223 A).

Harris et al. discloses the use of hyaluronidase in an amount sufficient to cause corneal softening.

Harris et al. fails to disclose the use of hyaluronidase derived from *Streptomyces hyalurolyticus*.

Schwartz et al. discloses a method of intraocularly injecting a mixture of chrondroitin sulfate, hyaluronic acid and hyaluronidase derived from *Streptomyces*, see Column 7, lines 61-65.

It would have been obvious to one having ordinary skill in the art to have modified Harris et al.'s method by utilizing an alternative source of biocompatible hyaluronidase, such as hyaluronidase isolated from *Streptomyces* taught by Schwartz.

Additionally, Schwartz et al. does not specify the species of *Streptomyces* utilized, however the Examiner believes that it would have been obvious to one having ordinary skill in the art to have utilized *Streptomyces hyalurolyticus* as taught by Kaneko et al., as it was a readily known source of hyaluronidase.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Straus (US 4,759,746 A) in view of Schwartz et al. (US 5,792,103 A), and further in view of Kaneko et al. (US 3,728,223 A).

Straus discloses intraocularly injecting a local anesthetic mixture, such as 15 cc of 0.75% bupivacaine, 5 cc of 4% lidocaine HCl and 1 cc of hyaluronidase, Column 4, lines 62-65.

Straus fails to disclose the use of hyaluronidase derived from *Streptomyces hyalurolyticus*.

Schwartz et al. discloses a method of intraocularly injecting a mixture of chrondroitin sulfate, hyaluronic acid and hyaluronidase derived from *Streptomyces*, see Column 7, lines 61-65.

It would have been obvious to one having ordinary skill in the art to have modified Strauss's method by utilizing an alternative source of biocompatible hyaluronidase, such as hyaluronidase isolated from *Streptomyces* taught by Schwartz.

Additionally, Schwartz et al. does not specify the species of *Streptomyces* utilized, however the Examiner believes that it would have been obvious to one having ordinary skill in the art to have utilized *Streptomyces hyalurolyticus* as taught by Kaneko et al., as it was a readily known source of hyaluronidase.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fedorov et al. (US 6,037,144 A) in view of Schwartz et al. (US 5,792,103 A), and further in view of Kaneko et al. (US 3,728,223 A).

Fedorov et al. disclose a method of using hyaluronidase for preparing artificial lenses.

Fedorov et al. fails to disclose the use of hyaluronidase derived from *Streptomyces hyalurolyticus*.

Schwartz et al. discloses a method of intraocularly injecting a mixture of chrondroitin sulfate, hyaluronic acid and hyaluronidase derived from *Streptomyces*, see Column 7, lines 61-65.

It would have been obvious to one having ordinary skill in the art to have modified Fedorov et al.'s method by utilizing an alternative source of biocompatible hyaluronidase, such as hyaluronidase isolated from *Streptomyces* taught by Schwartz.

Additionally, Schwartz et al. does not specify the species of *Streptomyces* utilized, however the Examiner believes that it would have been obvious to one having ordinary skill in

the art to have utilized *Streptomyces hyalurolyticus* as taught by Kaneko et al., as it was a readily known source of hyaluronidase.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard JMaynard
September 28, 2002

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
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